

EXHIBIT G

Serad, Danielle

From: Tom P. Cartmell <tcartmell@wcllp.com>
Sent: Friday, September 06, 2013 3:54 PM
To: Cameron, Roger; Jeff Kuntz; Andrew N. Faes; Bryan Aylstock; Renee Baggett; Daniel Thornburgh; Mary Liu; Ben Anderson; Balefsky, Lee; Ed Blizzard; Holly W. Gibson (hgibson@blizzardlaw.com)
Subject: RE: Summary and Analysis of "Due Diligence Summary Binder", Eth.mesh.09748308

Roger this and your earlier email are great. I am thinking we will likely need to draft either a letter or RFP for the documents that haven't been produced. Will you please handle? Actually, the more I think about it, let's just do an RFP so we can at least get formal answers. Bryan and Renee – do you agree?

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From: Cameron, Roger [mailto:Roger.Cameron@KlineSpecter.com]
Sent: Friday, September 06, 2013 12:05 PM
To: Tom P. Cartmell; Jeff Kuntz; Andrew N. Faes; Bryan Aylstock; Renee Baggett; Daniel Thornburgh; Mary Liu; Ben Anderson; Balefsky, Lee; Ed Blizzard; Holly W. Gibson (hgibson@blizzardlaw.com)
Subject: Summary and Analysis of "Due Diligence Summary Binder", Eth.mesh.09748308

This document is a treasure trove of substantive information about the acquisition of Medscand's TVT System and the shift of its manufacturing from Sweden to Neuchatel. It is also a road map for further avenues of discovery and proof of the multiple failures of JnJ to respond to our discovery requests and to manipulate the process to our prejudice.

Summary/Overview:

This document purports to be (but is not certainly) the Due Diligence Summary "Binder" for Project Tomel, sent 11/14/99 by Janice Kruger for Isabelle Billet, Growth Technologies/New Business Development, to Rodrigo Bianchi under separate overnight cover. Eth.mesh.09748310. Project Tomel is the project for the transfer of

manufacturing of the TVT System from Medscand's Swedish facility to Neuchatel through the acquisition of the TVT System product line from Medscand.

Binder Contents:

The Binder consists of several related documents but does not document all of the internal documentations of Ethicon to authorize its representatives to acquire the TVT System from Medscand.

It consists of the following:

- * The previously mentioned email;
- * A signature page for "approvals" of the due diligence summary, variously dated from Eth.mesh.09748313;
- * 9/7/99 Memo from Howard I. Zauberman, Growth Technologies/New Business Development Department (Eth.mesh.09748315) to C. P. Holland, F. J. Ryan, D.R. Sheffield, J. T. Lenehan, the Consumer Pharmaceutical & Professional Operating Group Committee, R. Darretta and the Ethicon Executive Committee, with appended - Valuation and Financial Summaries, Pro Formas for income and tax savings per upside, downside, and base cases, and expenses, as well as an undated memo from Billet revising the financial models based upon the deal closing 11/15/99 instead of 11/1/99;
- * 10/21/99 Summary of Due Diligence Activities by Peter Zurecki, Tomel Team Coordinator from the Growth Technologies/New Business Development Department (Eth.mesh. 09748332), with appended Team List, a Duty, Roles and Responsibilities chart by functional unit, a Due Diligence Documents Received/Reviewed Check List (Eth.mesh.09748344), Due Diligence Memoranda from each functional group or department of Ethicon that took part in the Tomel Project due diligence project (New Business Development/Legal, Finance, Operations, Intellectual Property, R&D/GT, Regulatory, and Quality Assurance), except Quality Systems; and
- * Billet's copy of a Robert McNeany 10/19/1999 email announcing his designation as team lead for the Tomel project to integrate manufacturing from Medscand into Neuchatel.

Substantive Factual Information:

The documents basically confirm the terms of the deal that is evidenced by the recently produced agreements. My impression is that this deal was a rushed, work in progress, because of the number and scope of the unresolved issues such as translating the DHF/TFs from Swedish into English and French, and the numerous other issues identified in the functional team reports that were not resolved before closing.

Additionally-

- * While there is a brief description of the 1997 Licensing Agreement, there is no mention made of the \$400,000 bonus payable to Ulmsten upon his successful replication of his initial studies. [Query: Why would JnJ oblige Ulmsten to replicate his prior studies if Ulmsten had been using Ethicon Prolene for those "studies"? He had already published those clinical results in his own self-edited journal. Given JnJ's exceedingly low standard of scientific journalism (failures to disclosure financial interests, failure to disclose its involvement in actually writing the articles, hiring ghostwriters like Artabani), Ulmsten's pre-1997 work would certainly have been sufficient for marketing if he actually used Prolene mesh.]
- * The Zauberman approval/authorization memo of 9/7/99 discusses only superficially the unmet needs that should have been at the heart of this device acquisition. It is concerned primarily with speedily getting primacy in the marketplace and erecting barriers to competitive entry into the market and reducing costs from \$70/unit to \$15/unit, in order to obtain a gross profit percentage of 97%. Eth.mesh.09748315.

* Before the November 15, 1999 deal and presumably only after the 1997 Licensing Agreement, Ethicon sent the mesh to Medscand at no cost. Eth.mesh.0974833; Eth.mesh.09748360. There either was no supply agreement between Ethicon and Medscand to supply Prolene mesh or, if there was one, it was not reviewed by the due diligence team. There is no mention that Ethicon ever shipped Prolene to Medscand or Ulmsten before the 1997 licensing agreement.

* The majority owner (60% of the shares) was Dr. Stormby, who is not further identified (a probable failure to conduct an appropriate due diligence investigation). The binder reports that, during the investigation, Ethicon learned that Stormby was intending to divest his interest. However, there is no mention of the person(s) to whom Stormby was going to sell and what would be the corporate governance structure of Medscand after the sale of the TVT System product line. They specifically expected a change in control of Medscand in the foreseeable future. This would be an essential item of information for a proper due diligence where, as here, Medscand would have significant post-closing obligations to Ethicon until the estimated date of manufacturing transfer to Neuchatel at the end of the second quarter of 2000. Other shareholders were Prof. Ulmsten (20%) and Mr. Johansson, Managing Director (20%). Eth.mesh.09748316.

* Analysis of the competition indicates that Ethicon was banking on the use of local anesthesia as a product sales motivator and that the recovery time would be merely two weeks. Eth.mesh.09748316. This contrasts somewhat with their representation to the FDA in the 510(k) that did not speak to any restraint from work in their initial filing but, in response to the FDA's comment that patients should avoid physical strain for 2-3 months (Eth.mesh.08476217; T-3142), Ethicon proposed avoiding work for 1-2 weeks and heavy exercising for 3-4 weeks (Eth.mesh.08476223; T-3142). It also contrasts with the general expectation, born out by use, that doctors would use general anesthesia.

* There is a reference to what can only be the unresolved at deal time issue of the "snowing" effect of particle loss in the Quality Assurance functional due diligence memo: "Supplier problem on the Mesh raw material causing approximately a 20% fallout of the raw material during use." No target date for completing the corrective action plan was given as of 10/5/99. Eth.mesh.09748381. This one seems odd because the binder clearly indicates that Ethicon was the supplier of the mesh at least after the Licensing Agreement. It does not seem to make a lot of sense to not mention Ethicon by name as the supplier in this part of the report or in the section addressing supplier qualifications, unless they really did not want to highlight their own involvement in that issue, perhaps to keep the information from shareholders of JnJ. Medscand, Librojo and Taylor are noted as the parties responsible for resolving the issue. Nothing in the binder evidences how this issue was resolved.

* The needle pull off issue existed at Medscand before the acquisition and the binder noted that resolving this issue was a prerequisite to closing. Eth.mesh.09748333.

* They claim that over 19,000 procedures were performed to date with 90% success rate (not defined) and minimal complications – implying that the clinical device used was the same and/or that Medscand sold all of the units implanted that comprise this 19,000 procedures figure. While there is no indication on the pro formas of a price per unit, this claim seems highly unlikely based upon the claim that in 1999 Medscand earned about \$4,000,000 on TVT sales. This would result in a \$210/unit price approximately, which is well below the figures provided through discovery so far. So either the procedure figure is inflated or the revenue figure underreported.

* There were significant gaps in the Quality Assurance functions at Medscand, including undocumented work practices and training instructions at Medscand that were to be satisfactorily memorialized in work instructions prior to closing. Eth.mesh.09748333.

* There are unexplained references to Projects Blue and Project Star. Eth.mesh.09748333.

* The Operations Department was supposed to have translated the specifications, audit the suppliers, obtain and prepare labeling changes and the DHF/TF.

* The responsibilities list is complete except for Quality Systems regarding DHFs, FMEA, Validations, etc. It appears that no one was responsible for this aspect of the investigation. Eth.mesh.09748342. No one was assigned responsibility for the Risk Assessment/Design Control Processes and Medical Device Vigilance Reports. Id. No one signed off on the corresponding portions of the Due Diligence Documents Received/Reviewed chart as having fulfilled these responsibilities, probably because the documents were in Swedish. The only bits of English language documents that they obtained were an index of the Design Control Quality Systems and complaint handling procedures. Eth.mesh.097489347-8.

* They made no assessment of product liability exposure, litigation reserves and never received a list of invention disclosures or know how that Ulmsten transferred to Medscand, let alone documentation of how those were transferred. Eth.mesh.09748345.

* No one from Medical Affairs had any involvement with the review of the clinical claims, adverse events or any other aspect of this acquisition.

Discovery and Investigation Issues:

Production -

Judging from the quality of the production (and my experience slaving over a copier for a few decades), this is not an original but a copy of a copy.

This appears in a footer to the Quality Assurance unit's memorandum of 10/12/1999 (Eth.mesh.09748378):
C:\Windows\Temp\due diligence_QA_Final_101299.doc. There are no other such legends on any of the document documents comprising the binder.

Design History File/Technical File -

Oral translations were supposedly provided contemporaneously with the due diligence investigation by Catrin Cederling of Ethicon and for the Regulatory Affairs functional team by Marguereta Eriksson, Medscand VP of RA/QA. These documents were in Swedish and the need for them to be translated into English (presumably for Somerville) and French (for Neuchatel) is noted as an issue that had to be resolved before closing.

Witnesses -

Numerous new witnesses and witnesses with newly revealed areas of knowledge are identified in this document.

1. The caption to a photo (eth.mesh.09748311) of the Team identifies On-Site team members as: Stewart Taylor, Peter Cecchini, Pierre Zurecki, Catrin Cederling, Isabelle Billet, Joern Lehe, Reynaldo Librojo, Ed Barabas and Carlos Cortes. Absent : Kent Sangrayr. Off-site team members : Bob McNeany, Verne Kreger, Jayne Zall, and Ken O'Gorman
2. A second list of team members (eth.mesh.009748336) identifies all of these individuals, along with their functional group and the team leadership:

Project Leader	Isabelle Billet - New Business Development
Team Co-ordinator	Pierre Zurecki - GT/New Business Development
Team Members	Ed Barabas - Operations
	Peter Cecchini - Regulatory Affairs
	Carlos Cortes - Finance
	Verne Kreger - Legal
	Jorn Lehe - R&D Europe
	Reynaldo Librojo - Q.A.

Bob Mc Neany - Operations
Kent Sangmyr - Legal
Stewart Taylor - Q.A.
Jayne Zall – Legal

This list omits Catrin Cederling and Ken O’Gorman. Also Zauberman’s approval memo indicates that there were 13 members of the due diligence team, but the mathematics for this claim do not work out.

3. Approvers of the Due Diligence Summary Binder were Cliff Holland (Pres. Ethicon); John Paulson (RA, Clinicals, QA); Sylvia Liu (R&D); Rich Sofinowski (Operations); Barbara Schwartz (Marketing); Rodrigo Bianchi (Marketing); David Kurlander (Finance); and Howard Zauberman (NBD/Growth Technologies). Eth.mesh.09748313.

4. The folks involved in the transfer of manufacturing to Neuchatel include: McNeany, Robert; Cousins, Bruce; Driver, Ken; Inamoto, Loretta; Fox, Lawrence; Walsh, Gerard; Billet, Isabelle; Angelini, Laura; Jones, Greg; Rossetti, Alessandro; Hoepffrier, Dr. Hans-Jochen; McMahon, Julie; Liu, Sylvia; Zauberman, Howard; Kurlander, David; Paulson, John; Sofinowski, Rich; Schwartz, Barbara; Barabas, Ed. Eth.mesh.09748384.

5. There are a number of other people involved in this acquisition and/or manufacturing transferring.

Especially noteworthy is Joerg Holste. Holste was not listed in the 2 “official” lists of team members that first appear in this document. His name is buried under the Due Diligence Checklist and this excerpt from page/Eth.mesh.09748342 (within the Due Diligence Summary, Eth.mesh.09748308) shows that he was involved in critical aspects of the due diligence and charged with the following responsibilities:

GT/R&D (Peter Cecchini , Jorg Holste, Joern Lehe)

- stability studies, materials qualification
- Pre-clinical data
- Clinical data

I did a word index search of his 4 days of testimony (NJ and MDL). He was not asked about Medscand or “diligence,” “purchase,” “buy,” or “acquire,” and his only Ulmsten related discussions had nothing to do with the Medscand acquisition. However, he did not write up the functional team report for R&D. Peter Cecchini of RA did. Also, that report merely adopts the biotoxicity and cytotoxicity reports appended to the 510(k) for classic TVT without any further analysis. So, while it seems that he may have some critical information, it is not a certainty that he does based on this bible. Either way, it would have been preferable to have had this document in hand before his deposition.

Greg Jones received copies of both the R&D Due Diligence report and the Regulatory Affairs Due Diligence report.

6. Also notable is Laura Angelini was part of the Tomel project team so far as it concerned the transfer of manufacturing to Neuchatel. Eth.mesh. 09748384. I don’t know who is on the team for deposing Angelini but I believe this email should be forwarded to them for possible use in Angelini’s upcoming deposition.

Missing Documents -

* There has been no production of any of the underlying Medscand documentation that was supposed to be and/or was acquired through the course of the due diligence investigation, including Swedish language DHF/TFs, specs, lists of component suppliers, representations by Medscand and/or Ulmsten provided as far back as June, 1999. They were supposed to obtain the Swedish language copies of all of these documents. Eth.mesh.09748333.

* There has been no production of any interim JnJ documentation of the actual investigation, such as emails between team members, drafts of the functional team reports and/or the summary, or correspondence with Medscand requesting documents, inspection dates, etc.;

- * All corporate actions in response to the request for approval to proceed with the acquisition are missing. There is no Letter of Intent to memorialize the terms of the deal pending closing. There is no documentation of the actions of the people and committees from whom Zauberman requested approval/authorization to conclude the deal. There are no motions, resolutions, minutes, authorizations or other typical corporate committee actions in response to Zauberman's request for authority to conclude the deal.
- * A manufacturing integration team "task/assignment" list appears as an icon on the last page of McNeany's email. Eth.mesh.009748385. This list is not attached and has not been produced;
- * All documents concerning the preparation and circulation of the binder for approval before Billet sent it to Rodrigo Bianchi on 11/14/99, the day before the deal closed;
- * Functional final report of Quality Systems, which unit was identified in the task/assignment chart is missing;
- * The existence of this binder begs the question of where is the due diligence report and supporting documents for the Licensing Agreement?
- * There is no documentation of the underlying agreement, if written (and many of Medscand's supplier contracts are noted to oral agreements), between Ulmsten and Medscand licensing or selling Ulmsten's patented rights to the production of "TVT" to Medscand before JnJ obtained its 1997 license for those rights, including also no manufacturing or design history documents that would have had to be part of the arrangement between Ulmsten and Medscand;
- * There was supposed to have been a manufacturing agreement between Medscand and Ethicon to cover Medscand's continued manufacturing after the closing until the start up of manufacturing at Neuchatel. This was not produced; and
- * Although Medscand was a private company, there are no financial documents provided or even mentioned, except for chattel mortgages on some unidentified production equipment. Standard banking practices would require at least that Medscand give over certified financial statements, amortization tables, etc. to their lenders so that their lenders can be assured that their collateral fully secures their debts. Standard due diligence investigations would require that such documents would be turned over to JnJ. The use of the word, "approximately," to describe Medscand's revenue suggests that there were no such documents provided. Else, exact figures should have been used.

Waiver of Privilege/Redactions -

There should be no redaction in the summary as it is not on its face a privileged communication. There was no approval of this binder by any attorney. Eth.mesh.09748313. And, certainly, there was no indication that the summary was even sent to an attorney, let alone sent with a request for advice.

The 10/14/99 memorandum of Kent Sangmyr from Advokatfirman (Google translate: "law firm") Delphi & Co. (eth.mesh.09748350) is reproduced with redaction. We may have an issue waiver here.

The 3 page redaction beginning at Eth.mesh.09748339 has no validity on the face of the document.

Production Source -

The document source, per the metadata, is indicated as, "New Business Development Department, related to TVT and Medscand." There is no such department. It begs the question where did this come from and why did they wait until now to survey the New Business Development Department of whichever JnJ entity this came from to obtain this document.

Reproduction of this Document -

This document is clearly a copy of a copy produced in prior litigation. It shows reduced size images from the binder with the legend in the margin not overwriting the image, as almost all of their other produced documents do. The redaction format is not consistent with the MDL protocol. This document simply has black-outs, without the word, redacted. The protocol uses white-outs with the word, redacted in it. This document is really a poor quality reproduction, that, from my experience, appears to have been a copy of a copy. This conclusion is supported by the next section of the email, Annotations and Reproduction. Just ask them to give you complete copies of all of the binder tabs, text bleeds off of the page, and illegible notes. They won't be able to, because they don't have the original. Ask them for the description they propose to include in the redaction log. They won't be able to come up with one, because they don't know what was redacted as they don't have the originals.

Annotations and Reproduction:

A minor cut off of a hand written note appears on Eth.mesh.09748313. A potentially more significant one appears on eth.mesh.09748375, where a post-it with handwritten notes appears. The notes are not legible to me (and that is probably further evidence that this is a copy of a copy . . .) Of minor concern, the binder tabs are not completely reproduced; some are completely cut off, some only partially reproduced.

Notable:

Ulmsten was working on a pelvic floor muscle function diagnostic device at that time but Ethicon was not interested in purchasing or developing it. Eth.mesh.09748370. Please recall that Ethicon has not, to my understanding, produced any documents concerning the strength of the forces applied to the pelvic floor by activities of daily living or more strenuous activities. They might have been able to support their claims if they bought this diagnostic device!

Conclusion:

There is certainly more to tell about this document and I would be happy to supplement this email with whatever information you might want. I would be happy to assist in any follow to this issues raised here.

Roger

Roger P. Cameron, Esquire
Direct: 215-772-1408